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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/394,230	09/13/1999	KEVIN L. GUNDERSON	393382001600	3919

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EXAMINER	
FORMAN, BETTY J	
ART UNIT	PAPER NUMBER
1634	34

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/394,230	GUNDERSON ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 18 November 2002 has been entered.

2. This action is in response to papers filed 18 November 2002 in Paper No. 18 which requested that amendments filed in the After-Final Response of 22 October 2002 be entered. The After-Final Response amended Claims 1, 11, 12 and 18. The After-Final amendments have been thoroughly reviewed and entered. The previous rejection in the Office Action of Paper No. 26 dated 13 June 2002 of Claims 1-11 under 35 U.S.C. 112, first paragraph and of Claims 1-18 under 35 U.S.C. 35 U.S.C. 103(a) are withdrawn in view of the amendments. The previous rejection of Claims 12-18 under 35 U.S.C. 112, first paragraph are maintained. All of the arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection.

New grounds for rejection are discussed.

Claims 1-18 are under prosecution.

Specification

3. The amendment filed 28 March 2002 in Paper No. 25 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

The amendment of Paper No. 25 adds the recitation "wherein each n-mer is at least 8 nucleotides in length" to independent claims 1 and 12. The recitation was deleted from Claim 1 in the amendments of Paper No. 29, but remains in Claim 12. The specification as filed fails to define or provide any disclosure to support such claim recitation. Applicant points to pages 11, 13 and 17 of the specification for support for the newly added limitation. However, theses pages do not provide support for the new limitation. Specifically, page 11, recites n-mer ranges of "from about 4 to about 50 nucleotides", "from about 5 to about 20 nucleotides", "from about 6 to about 12 nucleotides and most preferably from 8 to 9 nucleotides"; page 13 teaches the n-mer wherein n is 8; and page 17 teaches the n-mer wherein n =8 and ranges of "from about 6 to about 12 and more preferably, from about 8 to 9 nucleotides". The originally filed specification does not describe the limitations of the "at least 8 nucleotides". Therefore, the limitations introduces new matter into the disclosure.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 12-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

a. The recitation "wherein each n-mer is at least 8 nucleotides in length" is added to the amended independent claim 12. However, the specification fails to define or provide any disclosure to support such claim recitation. Applicant points to pages 11, 13 and 17 of the specification for support for the newly added limitation. However, theses pages do not provide support for the new limitation. Specifically, page 11, recites n-mer ranges of "from about 4 to about 50 nucleotides", "from about 5 to about 20 nucleotides", "from about 6 to about 12 nucleotides and most preferably from 8 to 9 nucleotides"; page 13 teaches the n-mer wherein n is 8; and page 17 teaches the n-mer wherein n =8 and ranges of "from about 6 to about 12 and more preferably, from about 8 to 9 nucleotides". The specification does not provide support for the "at least 8 nucleotides" because the newly added limitation does not have an upper limit (see MPEP, 2163.05, III).

With respect to changing numerical range limitations, the analysis must take into account which ranges one skilled in the art would consider inherently supported by the discussion in the original disclosure. In the decision in In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976), the ranges described in the original specification included a range of "25%- 60%" and specific examples of "36%" and "50%." A corresponding new claim limitation to "at least 35%" did not meet the description requirement because the phrase "at least" had no upper limit and caused the claim to read literally on embodiments outside the "25% to 60%" range, however a limitation to "between 35% and 60%" did meet the description requirement

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cantor et al. (U.S. Patent No. 5,631,134, filed 5 June 1995) in view of Southern (U.S. Patent No. 5,700,637, filed 19 April 1994).

Regarding Claim 1, Cantor et al. teach a method of determining the presence of a mutation in a target polynucleotide comprising the steps of providing a polynucleotide probe array wherein each probe comprises a double strand region and a single stranded n-mer overhang region; hybridizing a target polynucleotide to said overhangs in the array to generate a target hybridization pattern; and determining the presence of a mutation in the target polynucleotide by analyzing hybridization patterns (Column 8, lines 1-12) wherein the probes are designed to identify mutations (Column 4, lines 5-8) wherein the a single stranded n-mer overhang region is "preferably" about 4 to 20 nucleotides in length (Column 5, lines 60-65) and wherein the set of probes on the array comprises every possible n-mer (Column 6, lines 3-5). Cantor et al. do not teach hybridizing a reference polynucleotide to a second array and determining the presence of a mutation by comparing the reference and target hybridization patterns. However, the comparison of reference and target hybridization patterns to determine the presence of a mutation was known and routinely practiced in the art at the time the claimed invention was made. Specifically, Southern teaches a similar method for determining

the presence of a mutation in a target polynucleotide comprising hybridizing a target polynucleotide to array and a reference polynucleotide to a second array (Column 7,lines 10-31) and determining the presence of a mutation by comparing reference and target hybridization patterns without sequencing the target polynucleotide (Column 3, lines 58-62) wherein the n-mer arrays are complete n-mer arrays (Column 6, lines 8-27). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the complete n-mer hybridization detection and analysis of Cantor et al. with the complete n-mer hybridization comparison analysis of Southern whereby comparing hybridization patterns reveals differences between the target and reference and eliminates the need for sequencing the target sequence (Column 3, lines 52-62) and wherein the hybridizations are extremely sensitive because complete n-mer hybridizations are performed under highly stringent conditions to discriminate between single mismatch sequences as taught by Southern (Column 10, line 57-67-Column 11, line 4) for the expected benefits of identifying mutations accurately, efficiently and economically i.e. identifying mutations under highly stringent conditions without the time and labor consuming sequencing reactions.

The claimed "wherein the method has a false positive rate of less than 1 per 3900bp" recites a property of the method. The recitation is not a method step for determining the false positive rate. Cantor and Southern are silent regarding the false positive rate. However, because the recitation is a property of the claimed method; because the recitation does not limit the method steps; and because Cantor and Southern teach the claimed method steps, Cantor and Southern teach the method as claimed.

> The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process claims and MPEP § 2141.02 with regard to inherency and rejections under 35 U.S.C. 103.

The preceding rejection is based on judicial precedent following In re Fitzgerald, 205 USPQ 594 because Cantor and Southern are silent with regard to a false positive rate. However, the false positive rate recited in Claims 1-18 is deemed to be inherent in the accurate diagnosis of Cantor (Column 10, lines 23-57) and Southern ((Column 3, lines 3-9) and sensitivity of single base detection Cantor (Column 10, lines 38-40) and Southern (Column 2, line 66-Column 3, line 3) because their sensitivity which detects a single base and which accurately diagnosis would inherently have an extremely low false positive rate. The burden is on applicant to show that the claimed false positive rate is either different or non-obvious over that of Cantor and Southern.

Regarding Claim 2, Cantor et al. teach the hybridized polynucleotide is ligated to the probe (Column 8, lines 8-9).

Regarding Claim 3, Cantor et al. teach the hybridized polynucleotide is ligated to the probe (Column 8, lines 8-9). Cantor et al. do not discuss the reference polynucleotide. However, reference polynucleotides were known to one of ordinary skill in the art as discussed above and the skilled practitioner would have known that for comparison purposes, a target and reference polynucleotide would be treated equally i.e. ligated to the probe.

Regarding Claim 4, Cantor et al. teach the overhangs have free 5' ends (Column 12, lines 46-49 and Fig. 1B).

Regarding Claim 5, Cantor et al. teach the overhangs have free 3' ends (Column 12, lines 38-45 and Fig. 1A).

Regarding Claim 6, Cantor et al. teach the n-mer comprises from about 4 to 50 nucleotides (Column 12, lines 57-60).

Regarding Claims 7-9, Cantor et al. teach the mutation is a single nucleotide mutation (Column 10, lines 38-40). Cantor et al. do not teach the single nucleotide mutation is a substitution (Claim 7), a deletion (Claim 8) and an insertion (Claim 9). However, one skilled in the art at the time the claimed invention was made would have known that the single

nucleotide mutations taught by Cantor et al. include the claimed substitution, deletion and insertion mutations.

Regarding Claim 10, Cantor et al teach the method wherein single nucleotide mutations are identified wherein the identification quickly, efficiently and easily detects inherited mutations which cause disease and DNA depended phenotype and somatic variations (Column 10, lines 38-45). Cantor et al. do not teach the target polynucleotide is selected from the recited sequences. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the method of Cantor et al. with the teachings of Cantor et al. to obtain the claimed invention because the skilled practitioner in the art would have been motivated with a reasonable expectation of success to apply the mutation detection teaching of Cantor et al. to sequences known to contain single nucleotide mutations for the obvious benefit of detecting clinically relevant mutations quickly, efficiently and easily as taught by Cantor et al.

Regarding Claim 11, Cantor et al. do not teach parallel arrays. However, Southern teaches the similar method wherein the arrays are arranged in parallel i.e. stripes (Column 7, lines 12-22) whereby numerous sequence variations are analyzed simultaneously wherein each stripe corresponds to a different sequence variation. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the single array of Cantor et al. with the parallel arrays (i.e. strips) of Southern for the expected benefit of analyzing numerous mutations simultaneously as taught by Southern (Column 7, lines 23-26).

8. Claims 12-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cantor et al. (U.S. Patent No. 5,631,134, filed 5 June 1995) in view of Southern (U.S. Patent No. 5,700,637, filed 19 April 1994), Yershov et al (Proc. Natl. Acad. Sci., USA, 1996, 93: 4913-4918) and Fodor et al (U.S. Patent No. 5,800,992, issued 1 Sept 1998).

Regarding Claim 12, Cantor et al. teach a method of determining relatedness two or more polynucleotides comprising the steps of providing a polynucleotide probe array wherein each probe comprises a double stranded region and a single stranded n-mer overhang region such that the over hangs in each array constitute a complete set of n-mers; hybridizing a target polynucleotide to said overhangs in the array to generate a hybridization pattern and analyzing the hybridization patterns (Column 8, lines 1-10) wherein the a single stranded n-mer overhang region is "preferably" about 4 to 20 nucleotides in length (Column 5, lines 60-65) and wherein the set of probes on the array comprises every possible n-mer (Column 6, lines 3-5). Cantor et al. do not teach the method comprising two identical arrays wherein the target polynucleotide is hybridized to one array and a second target polynucleotide is hybridized to a second array. However, the comparison of hybridization patterns to determine if two or more sequences are identical was known and routinely practiced in the art at the time the claimed invention was made. Specifically, Southern teaches a similar method for determining whether two or more target polynucleotides are identical comprising providing at least two identical polynucleotide probe arrays; hybridizing a first polynucleotide to one array stripe and a second polynucleotide to a second array stripe (Column 7,lines 10-31) and comparing the first and second hybridization patterns without sequencing the target polynucleotide (Column 3, lines 58-62). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the complete n-mer hybridization detection and analysis of Cantor et al. with the complete n-mer hybridization comparison analysis of Southern whereby comparing hybridization patterns reveals differences between sequences and eliminates the need for sequencing the sequences (Column 3, lines 52-62) and wherein the hybridizations are

extremely sensitive because complete n-mer hybridizations are performed under highly stringent conditions which discriminate between single mismatch sequences (Column 10, line 57-67-Column 11, line 4) for the expected benefits of determining sequence similarity accurately, efficiently and economically i.e. determining sequence similarity under highly stringent conditions without the time and labor consuming sequencing reactions.

The claimed "wherein the method has a false positive rate of less than 1 per 3900bp" recites a property of the method. The recitation is not a method step for determining the false positive rate. Cantor and Southern are silent regarding the false positive rate. However, because the recitation is a property of the claimed method; because the recitation does not limit the method steps; and because Cantor and Southern teach the claimed method steps, Cantor and Southern teach the method as claimed.

The preceding rejection is based on judicial precedent following In re Fitzgerald, 205 USPQ 594 because Cantor and Southern are silent with regard to a false positive rate. However, the false positive rate recited in Claims 1-18 is deemed to be inherent in the accurate diagnosis of Cantor (Column 10, lines 23-57) and Southern ((Column 3, lines 3-9) and sensitivity of single base detection Cantor (Column 10, lines 38-40) and Southern (Column 2, line 66-Column 3, line 3) because their sensitivity which detects a single base and which accurately diagnosis would inherently have an extremely low false positive rate. The burden is on applicant to show that the claimed false positive rate is either different or non-obvious over that of Cantor and Southern.

The examples of Cantor et al illustrate arrays comprising all possible n-mers wherein each n-mer is 5 nucleotides in length. While Cantor et al do not teach specific embodiments wherein each n-mer is at least 8 nucleotides in length, probe microarrays comprising probes having a complete set n-mers wherein each n-mer is at least 8 nucleotides in length was well known in the art at the time the claimed invention was made as taught by Yershov et al and Fodor et al. Specifically, Yershov et al teach a microarray comprising all possible 8-mers is a

simple matter using robotic manufacturing means (page 4917, right column, last paragraph) and Fodor et al teach microarrays comprising all possible n-mers wherein each n-mer is at least 8 nucleotides in length (Column 17, line 49-Column 18, line 15) wherein the complete set of 8-mers are provided on a microarray of less then 1 cm^2 (Column 7, lines 61-67). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to scale up the microarray of Cantor et al by increasing the size/length of the n-mers to at least 8-mers as taught by Yershov et al and Fodor et al thereby providing a microarray comprising a complete set of n-mers wherein each n-mer is at least 8 nucleotides to thereby provide for batch hybridization of target to the microarrays comprising all possible n-mers for the expected benefits of automated, simple and reproducible hybridizations and mutation detection as taught by Fodor et al (Column 19, lines 35-65). The skilled practitioner in the art would have been reasonably motivated to scale up the microarray of Cantor et al based on the teaching of Yershov et al where they teach scaling up is a simple matter using know robotic manufacturing means (page 4917, right column, last paragraph).

The courts have stated that "mere scaling up of a prior art process capable of being scaled up, if such were the case, would not establish patentability in a claim to an old process so scaled." 531 F.2d at 1053, 189 USPQ at 148; In re Rose, 220 F.2d 459, 105 USPQ 237 (CCPA 1955); In re Rinehart, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976) see MPEP, 2144.04, IV, A.

Regarding Claim 13, Cantor et al. teach the hybridized polynucleotide is ligated to the probe (Column 8, lines 8-9).

Regarding Claim 14, Cantor et al. teach the hybridized polynucleotide is ligated to the probe (Column 8, lines 8-9). Cantor et al. do not discuss the reference polynucleotide. However, reference polynucleotides were known to one of ordinary skill in the art as discussed above and the skilled practitioner would have known that for comparison purposes, a target and reference polynucleotide would be treated equally i.e. ligated to the probe.

Regarding Claim 15, Cantor et al. teach the overhangs have free 5' ends (Column 12, lines 46-49 and Fig. 1B).

Regarding Claim 16, Cantor et al. teach the overhangs have free 3' ends (Column 12, lines 38-45 and Fig. 1A).

Regarding Claim 17, Cantor et al. teach the n-mer comprises from about 4 to 50 nucleotides (Column 12, lines 57-60).

Regarding Claim 18, Cantor et al. do not teach parallel arrays. However, Southern teaches the similar method wherein the arrays are arranged in parallel i.e. stripes (Column 7, lines 12-22) whereby numerous sequence variations are analyzed simultaneously wherein each stripe corresponds to a different sequence variation. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the single array of Cantor et al. with the parallel arrays (i.e. strips) of Southern for the expected benefit of analyzing numerous mutations simultaneously as taught by Southern (Column 7, lines 23-26).

Response to Arguments

9. Applicant argues that Cantor does not teach a false positive rate of less than 1 per 3900 bp. Applicant points to Column 16, lines 40-60 stating that the method of Cantor provides a false positive rate of 25%. The argument has been considered but is not found persuasive because while the one example cited by Applicant illustrates "ambiguous" signal for two hybrids, Cantor does not teach the ambiguous signal is a false positive signal as claimed. Furthermore, as stated above, Cantor clearly teaches that the method accurately diagnoses single nucleotide mutations (e.g. Column 10, lines 38-40) and because their sensitivity which detects a single base and which accurately diagnosis inherently has an extremely low false positive rate.

Applicant argues that Southern does not teach a false positive rate of less than 1 per 3900 bp. Applicant cites Southern for teaching that distinguishing a positive from a negative hybridization event is difficult and points to Fig. 3 and 4. The argument has been considered but is not found persuasive for several reasons. First, Applicant has not pointed to the passage in the Southern patent which support the allegation that distinguishing a positive from a negative hybridization event is difficult. Second, the Southern patent contains no figures and therefore Applicant's reference to the figures of Southern are not relevant to the patent. Finally, as stated above, Southern teaches their method is diagnostic (Column 3, lines 3-9) provides the sensitivity of single base detection (Column 2, line 66-Column 3, line 3). Because their sensitivity detects a single base and accurately diagnoses their method would inherently have an extremely low false positive rate.

Applicant further argues that Yershov and Fodor do not teach a false positive rate of less than 1 per 3900 bp. The arguments have been considered but are not found persuasive for the reasons stated above i.e. the sensitivity and diagnosis of Cantor and Southern would inherently have an extremely low false positive rate.

Prior Art

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Deugau et al (U.S. Patent No. 5,508,169, issued 16 April 1996) teach a method for identifying a polynucleotide comprising a probe array wherein each probe comprises a double stranded region and a single-stranded n-mer region (Column 9, lines 4-53 and Column 10, lines 45-51).

Conclusion

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
January 8, 2003